

Remarks

Applicants' Election

The examiner has restricted applicant's claims as defining **twenty-three** separate inventions. Applicants, **with traverse**, provisionally elected Group IV, claims 5, and 9-25, which is drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is spinocerebellar ataxia type 1, classified in class 604, subclass 891.1

Additionally, Applicant was required under this selection to elect a single mRNA target, recited in claims 16-22, and a single small interfering RNA sequence, recited in claim 23, wherein the elected mRNA target sequence must correspond to the elected siRNA sequences.

Applicants elect the mRNA target SCA1 as therapy for Spinocerebellar ataxia type I as recited in claim 19, and the single small interfering RNA sequence recited in claim 23 generated from SEQ IDs 1 and 2 (also referred to in the specification as AT0945).

Applicants reserve the right to file one or more future divisional applications, should Applicants' request to remove the present restriction requirement not be granted.

Applicants Traverse

MPEP § 803 states that the two requirements for restriction are:

- (1) The inventions must be independent or distinct as claimed; and,
- (2) [T]here must be a serious burden on the examiner if restriction is not required."

Applicant respectfully requests reconsideration and withdrawal of the present restriction requirement based on that the Examiner has not satisfied either of the requirements for restriction. It is respectively indicated that the Examiner must question whether the process the Examiner applied has lead to a correct result in that the Examiner has concluded that their are 23 separate and distinct inventions, thereby requiring 23 separate searches.

First applicants challenge that the Examiner has properly shown that the inventions are independent or distinct. In fact the Examiner's own selections show strong overlapping of subject matter that is not distinct and separate (see table on page 5). Applicants will concede there are several inventions posed in applicants' specification, but believe more logical groupings can be made for restriction.

Applicants have elected with traverse, group IV. However, Applicants argue that under the present restriction groups IV, XIII, XX to spinocerebellar ataxia type 1 can be combined together (It is also believed that groups V, XIV, XXI to spinocerebellar ataxia type II, and spinocerebellar ataxia type III, groups VI, XV, XXII could also be included with the original grouping).

IV. Claims 5, and 9-25¹, drawn to medical systems for treating a neurodegenerative disorder, wherein said neurodegenerative disorder is spinocerebellar ataxia type 1, classified in class 604, subclass 891.1.

XIII. Claims 31-40, 44, and 48-67 drawn to methods of treating neurodegenerative disorders, comprising intracranial delivery of small interfering RNA, and to methods of delivering small interfering RNA to specific locations in the brain, wherein the neurodegenerative disorder is spinocerebellar ataxia type 1.

XX. Claims 74, 78-84, drawn to small interfering RNAs, and to DNA sequences encoding small interfering RNAs, wherein the small interfering

¹ Claims 5, 9-25 dependent to claim 1, wherein it is provide there is a intracranial access device for delivering small interfering RNAs to locations within the brain.

RNA is hybridizable to an RNA sequence encoding a protein associated with spinocerebellar ataxia type 1, classified in class 536, subclass 24.5.

In order to make the restrictions, the Examiner has read out elements of claims (see footnotes) in order to argue the claims are distinct and different. Basically, all the cited claims require that there is a small interfering RNA, for treatment of spinocerebellar ataxia, delivered to the brain, by an intracranial access device.

It remains questionable whether searching all the spinocerebellar ataxia types are independent and distinct enough requiring that **nine** independent and distinct searches are required to determine patentability of the claims for this group of diseases.

Even if the invention includes claims to distinct or independent inventions, "[i]f the search and examination of an entire application can be made without serious burden", MPEP § 803 requires that the examiner "must examine [the entire application] on the merits." The Examiner may show that an undue burden is faced by demonstrating that separate searches are required. However, that burden is rebuttable.

The Examiner has indicated that effectively 23 independent searches are required. Applicants respectively suggest that far less than 23 searches is required. For instance, the following groupings can be made based on the disease being treated² (6 groups: 5 for diseases plus 1 for pumps) or based on each class and subclass searched (4 groups). Four to six searches should be enough.

Groups	Disease/Pumps	Class I	Class II	Class III
I, X XVII	Parkinson's	Class 604, subclass 891.1	Class 514, subclass 44	Class 536, Subclass 24.5
II, XI XVIII	Alzheimer's	Class 604, subclass 891.1	Class 514, subclass 44	Class 536, Subclass 24.5
III, XII, XIX	Huntington's	Class 604, subclass 891.1	Class 514, subclass 44	Class 536, Subclass 24.5
IV,XIII, XX	Spinocerebellar ataxia type I,	Class 604, subclass 891.1	Class 514, subclass 44	Class 536, Subclass 24.5
V, XIV, XXI	Spinocerebellar ataxia type II	Class 604, subclass 891.	Class 514, subclass 44	Class 536, Subclass 24.5
VI, XV, XXII	Spinocerebellar ataxia type III	Class 604, subclass 891.	Class 514, subclass 44	Class 536, Subclass 24.5
VII, XVI XXIII	Dentaorubral- pallidoluyism	Class 604, subclass 891.1	Class 514, subclass 44	Class 536, Subclass 24.5
VIII, IX	Electromechanical Infusion Pump Osmotic Infusion Pump	Class 604, subclass 500		

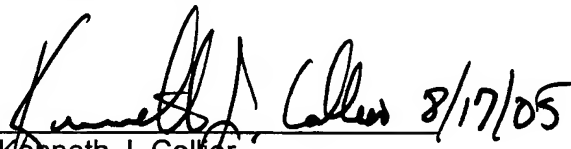
² Note that Spinocerebellar ataxia I, II, and III is being grouped as one disease.

Applicants have initially drawn to the examiner's attention that **nine independent** searches are required to adequately search the spinocerebellar ataxias. In another view, again in reference to the included table, it does not seem appropriate Applicants should be required to pay for the examiner to search Class 604, subclass 891.1 **seven times**, then search Class 514, subclass 44 **seven times**, and then search Class 536, Subclass 24.5 **seven times**.

Applicants assert that they have provided the Examiner with two proposed logical groups of the claims that does not require the excessive and redundant searching proposed by the Examiner. Applicants are not arguing their maybe several inventions contained in the disclosure, but question whether 23 independent searches are required.

In view of Applicants' reasoning to support their traverse of the restriction requirement, they respectfully request that groups IV, XIII, XX to spinocerebellar ataxia type 1 can be combined together (It is also believed that groups V, XIV, XXI to spinocerebellar ataxia type II, and spinocerebellar ataxia type III, groups VI, XV, XXII could also be included with the original grouping to spinocerebellar ataxia I).

Respectfully submitted,



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